Risk Assessment Report Review

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Background

The primary goal for environmental sites is to achieve environmentally protective site closeouts that meet applicable or relevant and appropriate requirements. Risk assessment, required under CERCLA, assesses if remediation is warranted and determines appropriate management of the hazard. These goals require the Air Force team to conduct and review risk assessments that are scientifically valid, legally defensible and consistent with reasonable future use. Risk assessment supports risk management decisions that must be health protective and cost effective. This presentation focuses on critical attributes of the risk assessment report. It will describe issues that risk assessment must address and how to verify whether the risk assessment is: representative of site conditions; relevant to current and future land use; based on realistic and relevant exposure routes, reasonable exposure parameters and exposure point concentrations representative of exposure domain.

This review will answer the question, "How do I make sure I get a 'good' risk assessment?" We will discuss the knowledge and skills needed to effectively manage the assessment of human health risk in a manner that is based on sound, defensible science. A good risk assessment is representative of site conditions and includes relevant current and future land use. The exposure routes and exposure parameters should be realistic and reasonable. The exposure point concentrations for each constituent should be calculated based on the representative exposure domain. The purpose of the risk assessment is to quantify risks associated with the site; therefore, the risk assessment is "good" if it meets the above criteria, regardless of the actual numerical outcome.

Discussion

A "good" risk assessment begins with good planning. Ideally, the risk assessor will be involved from the time of initial sampling plan development to assure that information needed to accurately assess risk is collected in the field. The risk assessor's involvement during the risk assessment scoping process is crucial. The earlier the risk assessor is involved, the easier it is to develop the risk assessment. Site visits can be extremely important in developing exposure scenarios. Make a plan and follow it.

Preparing for the Risk Assessment

During the scoping process, the risk assessor will assist in determining the data needed for modeling. The type and location of background samples will be selected and the preliminary identification of exposure routes (to assure that the appropriate data is collected). The selection of appropriate laboratory methods to achieve detection limits sensitive enough to evaluate risk is very important. Also, ensure that the risk assessor reviews and approves the sampling and analysis plan. Many dollars are burned by having to repeat work in order to perform the risk assessment. Inappropriate detection limits, no collection of surface soil samples, and failure to collect representative background samples for inorganic constituents are the most common errors that require additional sampling.

During sampling, communicate with the risk assessor, particularly if it appears that unexpected results are being obtained. Provide the risk assessor with any preliminary sampling results to determine if sampling needs to be refocused. It is wise to develop a good working relationship with the risk assessor to prevent miscommunication. Two-way communication should be developed so that as risk information becomes available that could impact risk management decisions, that information is supplied to the RPM. If significant changes in the potential land use, etc. are possible, notify the risk assessor as soon as possible.

During the risk assessment it is important for the RPM to keep in touch with the risk assessor as the Contaminates of Concern (COC) list is developed. The RPM generally has more information on the site history and can assist in COC selection based on historical activity. The basis for selecting exposed populations and exposure pathways is also an important topic of conversation between the RPM and risk assessor.

- Develop the COC list (Table 3 RAGS D)
- Confirm the appropriate basis to exclude COCs
- Confirm alternate future land use
- Understand the basis for selection of pathways and exposed populations (Table 1 RAGS D)

Early in the process it is also important to get concurrence from the agency on modeling, any site-specific exposure assumptions, and the use of non-EPA-derived toxicity values. Also, discuss the appropriate level of detail and degree to which uncertainty will be quantified in the risk assessment with the agency.

Before completing the risk assessment and submitting the document to the agency for review, it is often useful to discuss with the agency how the pathways will be combined and how the hazard indices will be segregated based on target organ. This can save a considerable amount of time and money in rewriting risk assessments because substantial effort is required to write the justification of various professional decisions made while conducting the risk assessment. If you can verify that the agency agrees with the approach for combining risks and hazards before writing the report, there is less likelihood that the document will need to be rewritten. The RAGS D tables, which serve as interim deliverables, can assist in this task of obtaining concurrence on the approach.

As the data collection and evaluation is performed, review the conceptual site model to assure that it adequately describes the site. The risk assessment will be based on the conceptual site model, so accuracy at the early stage of the process is important. Don't wait until the risk assessment document is written to review the model. A DQO statement will assist in limiting the amount of additional data collected. Only additional data that could potentially change the conclusion that has been drawn should be collected.
Background samples should be identified in the sampling work plan. The number, location, and statistical procedures to be used for analysis should be provided. The sampling locations should be guided somewhat by the location of exposure activities. The type of exposure likely to occur will also determine the sampling depths (surface soil sampling for direct contact should be taken at 0-6" or 0-12" maximum).

HOW TO REVIEW A RISK ASSESSMENT

The RPM should be reviewing the basics. The scope of the risk assessment should be consistent with the complexity of the site. An extremely detailed risk assessment with every conceivable exposure pathway quantified may not be necessary for every site. Since the RPM generally has more knowledge on the site history, be sure to review the COC selection list and verify that site history adequately supports COC selection. The risk assessment should clearly be consistent with the approach developed during the scoping process.

A surprising number of risk assessments do not contain adequate figures depicting the sampling locations or the site relative to important landmarks. Verify that figures clearly show sample locations and the site location relative to receptors. Rely on guidance in RAGS D tables to guide your review. RAGS Part D provides tables to guide the review and format of the risk assessment document. This table format will be required for all CERCLA risk assessments. Additional tables may be presented (above and beyond those in RAGS D) if they assist in clarifying the information. The risk assessment will be based on the conceptual site model, so accuracy at the early stage of the process is important. Verify that data collection and evaluation is performed consistent with DQO statements and that site and background sample are sufficient to accurately represent site conditions. Verify that appropriate areas were sampled at the correct depths relevant to exposure areas. Clearly describe site characteristics as necessary to support modeling. Only additional data that could potentially change the conclusion that has been drawn should be collected.

Data Collection and Evaluation. It may be necessary to do additional sampling in "hotspot" areas. Be sure that the statistical procedures that will be used to assess the data are appropriate for biased sampling and that QA/QC data are provided. A DQO statement will assist in limiting the amount of additional data collected. Only collect additional data that could potentially change the conclusion that has been drawn.

Data Evaluation. Is the rationale for COC selection clear? Were appropriate detection limits used? Are data qualifiers reported in summary tables? Is the quantity of data with qualifiers excessive? Use of Table 2 from RAGS Part D will help assure that the appropriate data is recorded for selection and/or deletion of constituents from the COC list (or from the screening analysis).

Exposure Assessment. Is the reasonable maximum exposure (RME) defined? Are current and future land uses considered? Are potential sensitive subpopulations identified? Are contaminant release mechanisms and

migration pathways reasonable? Are Site-specific characteristics considered? Current and future land uses should be considered in the risk assessment. The future land use should be consistent with the reuse planned under BRAC or continued current use. Site-specific characteristics are very important. What barriers exist (such as runways or natural barriers) that change the appropriate exposure assumptions? Potential subpopulations should be identified (children under the age of seven for lead). Are spatial relationships of hotspots to areas of high exposure potential identified? Are the calculations of the concentration term correct? Are site-specific values and/or default values used correctly? RAGS Part A discusses the need to evaluate potential hotspot locations in relation to exposure potential. Hotspots can be important if they coincide with areas of high exposure.

Toxicity Assessment. The toxicity assessment must consider appropriate route-to-route extrapolations. Toxicity values must reflect the appropriate exposure duration (sub-chronic or chronic) and toxicity values are obtained from or consistent with IRIS. The IEUBK model is used for childhood lead exposure and adult guidance for lead in older children and adults.

Risk Characterization. Make sure that the summation of risks and hazards makes sense. Evaluate the approach and rationale for summing risks across exposure pathways and chemicals. Verify calculations for at least one calculation for carcinogens and one for non-carcinogens to assure that the spreadsheet is correct. It may not be appropriate to assume that the RME individual for one exposure pathway is also the RME individual for other exposure pathways. Sources of uncertainty should be identified in the risk characterization section. Qualitative and/or quantitative assessment of uncertainty must be performed.

Common sense is often your best guide. If exposure scenarios seem unreasonable for your site, or just too detailed, they probably are. For example, assuming significant ingestion of homegrown vegetables when the lot sizes are less than 1/4 acre may be unreasonable. It is quite common for errors of up to 3 orders of magnitude (for example milligrams to micrograms) to occur in calculations. Don't assume that the spreadsheet is always right - if the risk for your site seems higher or lower than you expected, verify the inputs and math. Use site-specific information when it is available to help assure that the calculated risks are representative of the site. This helps in risk communication.

Trust your instincts. Risk assessment is a formal process with rules; however, we can be creative and we must be realistic while following the rules. Ask questions, not only of your contractor, but also of the regulators. Don't be afraid to think outside the box. Just because things have always been done one way doesn't mean that there isn't another (and possibly better) way to do it.